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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/562,831

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Lene Moller

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EXAMINER

KIM, TAEYOON

ART UNIT

PAPER NUMBER

1651

NOTIFICATION DATE

DELIVERY MODE

04/16/2009

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

usptomailnyc@kslaw.com

Office Action Summary	Application No. 10/562,831	Applicant(s) MOLLER ET AL.	
	Examiner Taeyoon Kim	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 February 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3,5,10,11,14,15,17-19,21-24,27-30,33-45,47-63 and 86-101 is/are pending in the application.
- 4a) Of the above claim(s) 19,21-24,27-30,33-39 and 41 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,3,5,10,11,14,15,17,18,40,42-45,47-63 and 86-101 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/30/06; 2/15/08; 2/23/09</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1, 3, 5, 10, 11, 14, 15, 17-19, 21-24, 27-30, 33-45, 47-63 and 86-101 are pending.

Election/Restrictions

Per the interview on 2/2/2009, the previous requirement for restriction mailed on 11/28/2009 is withdrawn.

Claims 19, 21-24, 27-30, 33-39 and 41 are withdrawn from consideration as being drawn to non-elected subject matter. Claims 1, 3, 5, 10, 11, 14, 15, 17, 18, 40, 42-45, 47-63 and 86-101 have been considered on the merits.

Information Disclosure Statement

The information disclosure statement filed 2/15/2008 fails to comply with 37 CFR 1.98(a)(2), which requires a legible copy of each cited foreign patent document; each non-patent literature publication or that portion which caused it to be listed; and all other information or that portion which caused it to be listed. It has been placed in the application file, but the information referred to therein has not been considered. Only US patents and applications listed in the IDS were considered.

Specification

The specification is objected to as failing to provide proper antecedent basis for the claimed subject matter. See 37 CFR 1.75(d)(1) and MPEP § 608.01(o). Correction of the following is required:

Claims 44 and 47 disclose a negative limitation of “does not comprise collagen”. This limitation does not have a proper antecedent basis in the specification. There is no

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disclosure in the specification to support this limitation.

Claim Objections

Claim 11 is objected to because of the following informalities: Claim 11 discloses the term "USP 24". It is more appropriate to disclose a full name of the term followed by an abbreviation in a parenthesis. Appropriate correction is required.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1, 3, 5, 10, 11, 14, 15, 17, 18, 42-45, 47-63 and 86-101 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 1 discloses the term "or a derivative thereof" in line 2. It is not clear whether the term "thereof" is referring gelatin and hyaluronic acid, or it refers only hyaluronic acid. According to the specification, it appears that the term "thereof" indicates hyaluronic acid. However, it is vague in the claims. Clarification is required.

Claim 11 discloses the term "USP 24". It is not clear what the term intends to point out. It appears that the term indicates a publication on National Formulary from United States Pharmacopeia, however, the specification does not clearly point out what the subject matter of the term is. Clarification is required.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that

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form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1, 3, 5, 10, 11, 17, 40, 42-45, 47, 51, 57, 60, 61, 62, 63, 86, 89, 92, 95, 98 and 101 are rejected under 35 U.S.C. 102(b) as being anticipated by Choi et al. (1999; J. Biomed. Mater. Res.).

Choi et al. teach a gelatin-hyaluronic acid (HA) sponge comprising gelatin and HA in a form of sodium hyaluronate (a salt form) in a ratio of 9:1, 7:3 or 5:5, cross-linked chemically with a cross-linking agent such as EDC (1-Ethyl-(3-(3-dimethylaminopropyl) carbodiimide hydrochloride), or physically by thermal heating, and freeze-dried (p.631-632; Materials and Methods). Choi et al. also teach the molecular weight of HA being 1700 kDa and pH being 6.36 (Materials and Methods).

With regard to the limitation of claim 10 drawn to the sponge absorbing less water than an absorbable gelatin sponge or the limitation of claim 11 drawn to the ratio between the water absorbed by the composition and the water absorbed by an absorbable gelatin sponge being at the most 0.95 when determined in accordance with USP 24, this limitation is merely drawn to the property of the composition rather than the structural limitation to the composition. Since the composition of Choi et al. is considered substantially similar, if not the same, the property of the Choi et al.'s composition is expected to have the same property as the claimed invention.

M.P.E.P. § 2112.01 recites, "Products of identical chemical composition can not have mutually exclusive properties. A chemical composition and its properties are

inseparable. Therefore, if the prior art teaches the identical chemical structure, the properties applicant discloses and/or claims are necessarily present.” See *In re Spada* (citations omitted).

Claims 40, 42, 43 and 47 are product-by-process claims. M.P.E.P. § 2113 reads, “Product-by-process claims are not limited to the manipulations of the recited steps, only the structure implied by the steps.”

“Even though product-by-process claims are limited by and defined by the process, determination of patentability is based on the product itself. The patentability of a product does not depend on its method of production. If the product in the product-by-process claim is the same as or obvious from a product of the prior art, the claim is unpatentable even though the prior product was made by a different process.” *In re Thorpe*, 777 F.2d 695, 698, 227 USPQ 964, 966 (Fed. Cir. 1985) (citations omitted).

The structure implied by the process steps should be considered when assessing the patentability of product-by-process claims over the prior art, especially where the product can only be defined by the process steps by which the product is made, or where the manufacturing process steps would be expected to impart distinctive structural characteristics to the final product. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979)

The use of 35 U.S.C. §§ 102 and 103 rejections for product-by-process claims has been approved by the courts. “[T]he lack of physical description in a product-by-process claim makes determination of the patentability of the claim more difficult, since in spite of the fact that the claim may recite only process limitations, it is the patentability

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of the product claimed and not of the recited process steps which must be established.

We are therefore of the opinion that when the prior art discloses a product which reasonably appears to be either identical with or only slightly different than a product claimed in a product-by-process claim, a rejection based alternatively on either section 102 or section 103 of the statute is eminently fair and acceptable. As a practical matter, the Patent Office is not equipped to manufacture products by the myriad of processes put before it and then obtain prior art products and make physical comparisons therewith." *In re Brown*, 459 F.2d 531, 535, 173 USPQ 685, 688 (CCPA 1972).

Thus, the reference anticipates the claimed subject matter.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 1, 3, 5, 10, 11, 14, 15, 17, 18, 40, 42-45, 47-63 and 86-101 are rejected under 35 U.S.C. 103(a) as being unpatentable over Choi et al. (supra) in view of Della Valle et al. (US 4,851,521; IDS ref.) and Moore et al. (US 3,678,933).

Choi et al. anticipate the subject matter of claims 1, 3, 5, 10, 11, 17, 40, 42-45, 47, 51, 57, 60, 61, 62, 63, 86, 89, 92, 95, 98 and 101, and therefore, render them obvious (see above).

Choi et al. do not teach that the hemostatic sponge comprising ester of HA (claim 3).

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Della Valle et al. teach esters of HA or a salt thereof being used for medical use such as spongy materials (Example 42 in col. 50).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to substitute HA ester or a salt thereof for the sponge composition of Choi et al. as an art-recognized alternative or equivalent to HA.

Although Choi et al. do not particularly teach that the hemostatic sponge being covered by a top sheet (claim 14), it is extremely well known in the art that a surgical dressing or sponge employs a plastic film as a cover, and also Moore et al. teach the use of thin plastic film as a cover of surgical dressing or sponge (col. 1, lines 43-55).

Moore et al. teach a surgical sponge covered with a thin plastic film (abstract).

It would therefore have been obvious for the person of ordinary skill in the art at the time the invention was made to use the thin plastic film (cover) of Moore et al. in the sponge of Choi et al.

The skilled artisan would have been motivated to make such a modification because Moore et al. teach that the thin plastic film provides non-sticking, non-sliding surface and high rate of absorption (col. 1, lines 4-13).

The person of ordinary skill in the art would have had a reasonable expectation of success in using the plastic film cover/laminate of Moore et al. in the sponge of Choi et al.

Although Choi et al. in view of Moore et al. do not particularly teach the cover being removable, it would have been obvious to a person of ordinary skill in the art to make composition separable.

M.P.E.P. §2144.04 states if the facts in a prior legal decision are sufficiently similar to those in an application under examination, the examiner may use the rationale used by the court. Examples directed to various common practices which the court has held normally require only ordinary skill in the art and hence are considered routine expedients are discussed below. If the applicant has demonstrated the criticality of a specific limitation, it would not be appropriate to rely solely on case law as the rationale to support an obviousness rejection.

In re Dulberg, 289 F.2d 522, 523, 129 USPQ 348, 349 (CCPA 1961) (The claimed structure, a lipstick holder with a removable cap, was fully met by the prior art except that in the prior art the cap is "press fitted" and therefore not manually removable. The court held that "if it were considered desirable for any reason to obtain access to the end of [the prior art's] holder to which the cap is applied, it would be obvious to make the cap removable for that purpose.").

With regard to the limitation drawn to the composition of gelatin and HA being paste or powder, it would have been obvious to a person of ordinary skill in the art to try gelatin-HA sponge into a powder or a paste for different applications. It is considered that the format of the composition as sponge, powder or paste is merely an optional choice known in the art, and a person of ordinary skill in the art would try different, identified and predictable options.

The Supreme Court recently states in *KSR v. Teleflex* (550 US82 USPQ2d 1385, 2007) "The same constricted analysis led the Court of Appeals to conclude, in error, that a patent claim cannot be proved obvious merely by showing that the combination of

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elements was "obvious to try." *Id.*, at 289 (internal quotation marks omitted). When there is a design need or market pressure to solve a problem and there are a finite number of identified, predictable solutions, a person of ordinary skill has good reason to pursue the known options within his or her technical grasp. If this leads to the anticipated success, it is likely the product not of innovation but of ordinary skill and common sense. In that instance the fact that a combination was obvious to try might show that it was obvious under §103." See also M.P.E.P. §2141.

With regard to the limitation of percentage of gelatin and HA in the composition disclosed in claims 48-50, 52-56, 58 and 59, the range of percentage claimed is within the range of percentage for gelatin and HA in the sponge of Choi et al., and therefore, the reference renders the range obvious. Choi et al. teach the ratio of gelatin to HA being 9:1, 7:3 or 5:5, which is interpreted as gelatin being 50 to 90% and HA being 10 to 50%. Therefore, the claimed percentage for gelatin being at most 60 to 85% is within the range of gelatin (50 to 90%) taught by Choi et al. Similarly, the claimed percentage for HA being at most 15 to 40% is within the range of HA (10 to 50%) taught by Choi et al.

With regard to the limitation drawn to the composition not comprising collagen in claims 44 and 47, since the composition of Choi et al. which utilizes commercially available gelatin granule rather than collagen as a starting material, it is considered that the composition does not contain collagen.

Therefore, the invention as a whole would have been *prima facie* obvious to a

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person of ordinary skill at the time the invention was made.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taeyoon Kim whose telephone number is (571)272-9041. The examiner can normally be reached on 8:00 am - 4:00 pm ET (Mon-Thu).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Taeyoon Kim/
Examiner, Art Unit 1651